AUG 1 1 2000

K001940

Summary of Safety and Effectiveness

MICOR®, INC.
Anesthesia Conduction Kit

1.0 Micor Contact

Jeremiah Costello, Ph.D.
Micor, Inc.
2855 Oxford Boulevard
Allison Park, Pennsylvania 15101
Telephone: (412)487-1113
Facsimile: (412)487-1747

2.0 Device Name

2.1 Trade Name

Anesthesia Conduction Kit

2.2 Classification Name

Device Name:	Anesthesia, Conduction, Kit
Speciality:	Anesthesiology
Product Code:	73 CAZ
Device Class:	2
Regulation No.:	21 CFR 868.5140

3.0 Predicate Device

3.1 Alexander Medical Epidural Kit and Combined Spinal/Epidural Kit (K964783)

3.2 SIMS Inc. Regional Anesthesia Trays (K965017)

3.3 RŰSCH International Anesthesia Conduction Kit (K983125)

4.0 Product Description/Function

4.1 **Description** The subject device is substantially equivalent in design and performance characteristics to the Alexander Medical, SIMS and RŰSCH predicates.

4.2 **Function** The subject device will function the same as the predicate devices.

5.0 Comparison of the Subject Device and Predicate Devices for Equivalence

5.1 **General** Anesthesia conduction/epidural kits have been marketed since before the medical device amendments and many have received FDA clearance. These include kits by Becton Dickinson, Sims Portex, Preferred Medical and many other companies.

5.2 **Technological Characteristics** The technological characteristics of Micor's Anesthesia Conduction Kit, as compared to those of the Alexander Medical's, SIMS Inc. and RŰSCH International predicates, are essentially the same.

5.3 **Materials** The materials incorporated in the subject device are substantially equivalent to those common to and contained in the legally-marketed predicate, Alexander Medical's Epidural Kit and Combined Spinal/Epidural Kit. The Touhy Borst adaptor in Alexander Medical's Kit is manufacture by Micor from identical materials to the adaptor in the subject device. The Thread assist guide and stylet of the subject device are substantially equivalent in materials and function to these components in the predicate K983125.

5.4 **Intended Use** The subject device is equivalent to the predicates in its use for conduction, regional and local anesthesia. There are no new indications for use or claims made for the kit or the components in the kit.

5.5 **Conclusion** No new issues of safety or effectiveness are raised by the design of this device. Micor' Anesthesia Conduction Kit is equivalent to the cited predicate devices in its material, technology, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2000

Jeremiah Costello, Ph.D.
Micor Incorporated
2855 Oxford Boulevard
Allison Park, PA 15101

Re: K001940
Micor Anesthesia Conduction kit
Product Code: 73 CAZ
Dated: June 21, 2000
Received: June 26, 2000

Dear Dr. Costello:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the

Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K001940
510(k) Number (if known)

Anesthesia Conduction Kit
Device Name

(NOTE: These are appropriate indications for use for this device as established by the equivalent predicate devices.)

Indications for Use:

The Micor Anesthesia Conduction *Kit* is intended for administration of continuous epidural anesthesia.
Micor recommends that the catheter be removed or replaced every 72 hours.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of ~~CDRH, Office of Device Evaluation~~ (ODE)
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

B-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K001940